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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,173	10/16/2000	Karen W. Shannon	10990638-1	2834

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EXAMINER

HUDSON, AMY J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/690,173	<b>Applicant(s)</b> SHANNON, KAREN W.	
	<b>Examiner</b> Amy J Hudson	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41, 42, 46-63 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41, 42, 46-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### ***Claim Objections***

Claims 54 and 55 are objected to under 37 CFR 1.75 as being substantial duplicates of claims 51 and 52, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the claims mentioned are exact duplicates.

### ***Double Patenting Rejection***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 42, and 46-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 14, 26, and

28-31 of U.S. Patent No. 6,132,997. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain the same components, methods, and kit.

Instant claim 41 is directed to a kit for use in linearly amplifying mRNA. The components of the kit as claimed are: an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence, an RnaseH<sup>-</sup> polymerase, an RnaseH<sup>+</sup> polymerase, and a reverse transcriptase inhibitor. The kit of instant claim 53 contains the same components but specifies ddNTPs as the reverse transcriptase inhibitor and adds an RNA polymerase. The kit of instant claim 59 is directed to an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence; and a reverse transcriptase inhibitor. The components of the instant claimed kits are necessary in order to practice the method disclosed by U.S. Patent No. 6132997(claims 1, 4, 10, and 16). Therefore, the components of the instant claimed kit are obvious over the method disclosed in U.S. Patent No. 6132997.

Instant claims 42, 57, and 63 further include the instructions of the kit of claims 41, 53, and 59, respectively. The instructions are to convert mRNA to cDNA, and then to transcribe the cDNA into RNA in the presence of a reverse transcriptase that is rendered incapable of RNA-dependent DNA polymerase activity during the transcription step. U.S. Patent No. 6132997, claim 1, teaches a method for linearly amplifying mRNA, said method comprising: converting mRNA to cDNA, followed by transcribing the cDNA into RNA in the presence of a reverse transcriptase that is incapable of RNA-dependent DNA polymerase activity during said transcribing step. The method taught in

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claim 1 of U.S. Patent No. 6132997 corresponds with the steps of the instant instructions. The kit with instructions would therefore be obvious over the method claimed in U.S. Patent No. 6132997 since they each specify the same method, including similar instructions.

Instant claims 46-52, 54-56, 58, and 60-62 further limit the kits of instant claims 41, 53, and 59. Instant claims 46 and 58 read on the kit further comprising MMLV-RT. Instant claim 47 reads on the kit further comprising an RNA polymerase. Instant claims 48 and 56 specify the RNA polymerase to be T7 RNA polymerase. Instant claims 49-52, 54, 55, and 60-62 read on ddNTPs serving as the reverse transcriptase inhibitors. U.S. Patent No. 6132997 claims 1, 14, 18, 23, and 25 teach all of these components as a part of the claimed methods, therefore instant claims 46-52, 54-56, 58, and 60-62 are obvious over the methods claimed in U.S. Patent No. 6132997 since the components are previously taught and are needed to carry out the method as previously claimed.

The kit components of instant claims 41, 42, and 46-52 correspond with the steps of the methods claimed in U.S. Patent No. 6132997 claims 1-25. It would have been obvious to one skilled in the art at the time of filing to use the kit components in the method disclosed in U.S. Patent No. 6132997, since the components are intended to be used in such a method.

Additionally, the kit taught in U.S. Patent No. 6132997 claims 26-31 has overlapping scope with the kit being instantly claimed. Instant claim 53 reads on a kit for linearly amplifying mRNA, said kit comprising: an oligonucleotide promoter-primer

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comprising an RNA polymerase promoter sequence; an RnaseH- polymerase; an RnaseH+ polymerase; ddNTPs; and an RNA polymerase. Instant claim 53 is a species of broader claim 26 teaching a kit in U.S. Patent No. 6132997. U.S. Patent No. 6132997 claim 26 teaches a kit for use in linearly amplifying mRNA into antisense RNA, said kit comprising: and oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence; and ddNTPs. When considering the totality of the kit claims in U.S. Patent No. 6132997 (claims 26-31), every component of the instant claimed kit (instant claims 53-56) is accounted for in the kit of U.S. Patent No. 6132997, and thus obvious one over the other.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Hudson whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:30 am – 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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